



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request:

The Framingham Heart Study (FHS)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To request more

information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Gina Wei, Division of Cardiovascular Sciences, NHLBI, NIH, Two Rockledge Center, 6701 Rockledge Drive, MSC 7936, Bethesda, MD, 20892-7936, or call non-toll-free number (301) 435-0456, or e-mail your request, including your address to: weig@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: The Framingham Heart Study, 0925-0216, Extension, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Framingham Heart Study will continue to conduct morbidity and mortality follow-up, as well as examinations, for the purpose of studying the determinants of cardiovascular disease. Morbidity and mortality follow-up will continue to occur in all of the cohorts (Original, Offspring, Third Generation, Omni Group 1, and Omni Group 2). Examinations will continue to be conducted on the Original, Offspring, and Omni Group 1 Cohorts.

OMB approval is requested for 3 years. There is no cost to the respondents other than their time. The total estimated annualized burden hours are 4264.

Estimated Annualized Burden Hours, Original Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM				
a. Telephone contact to set up appointment	60	1	10/60	10
b. Exam Appointment, Scheduling, Reminder, and Instructions	55	1	35/60	32
B. EXAM – Cycle 32				
a. Clinic exam	25	1	45/60	19
b. Home or nursing home visit	25	1	65/60	27
C. ANNUAL FOLLOW-UP				
a. Records Request	60	1	15/60	15
b. Health Status Update	45	1	15/60	11
SUB-TOTAL:PARTICIPANT COMPONENTS	60*	-----	-----	114
II. NON- PARTICIPANT COMPONENTS				
A. Informant Contact (Pre-exam and Annual Follow-up)	25	1	10/60	4
B. Records Request (Annual follow-up)	50	1	15/60	13
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	75	-----	-----	17

* Number of participants as reflected in Rows I.A.a and I.C.a. above

Estimated Annualized Burden Hours, Offspring Cohort and Omni Group 1 Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM				
a. Telephone contact to set up apt or Health status update	300	1	10/60	50
b. Appt. or update Confirmation	250	1	10/60	42
c. Food Frequency Form	250	1	10/60	42
B. EXAM				
a. Clinic Exam	100	1	175/60	292
b. Home or nursing home visit	100	1	60/60	100
c. Consent Forms	200	1	20/60	67
C. ANNUAL FOLLOW-UP				
a. Records Request	2292	1	15/60	573
b. Health Status Update	1833	1	15/60	458
SUB-TOTAL: PARTICIPANT COMPONENTS	2292*	-----	-----	1624
II. NON- PARTICIPANT COMPONENTS				
A. Informant contact (Pre-exam and Annual Follow-up)	229	1	10/60	38
B. Records Request (Annual follow-up)	2292	1	15/60	573
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	2521	-----	-----	611

* Number of participants as reflected in Rows I.C.a. above

Estimated Annualized Burden Hours, Generation 3 Cohort and Omni Group 2 Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP		1		
A. Records Request	3212	1	15/60	803
B. Health Status Update	3212	1	15/60	803
SUB-TOTAL: PARTICIPANT COMPONENTS	3212*	-----	-----	1606
II. NON- PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP				
A. Informant contacts	160	1	10/60	27
B. Records Request	1060	1	15/60	265
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	1220	-----	-----	292

* Number of participants as reflected in Rows I.A. and I.B. above

Summary of 3 Tables Combined -Total Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
Participants	5564	1	36/60	3344
Non-Participants	3816	1	14.5/60	920
Totals	9380			4264

(Note: reported and calculated numbers differ slightly due to rounding.)

Dated: April 25, 2013.

Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

Michael Lauer,

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National Institutes of Health

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